

COMFORTIS- spinosad tablet, chewable
Elanco Animal Health Co

COMFORTIS®-Cats

(spinosad)

Chewable Tablets

For information on dogs, see reverse side.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

COMFORTIS (spinosad) is available in four sizes of chewable flavored tablets for oral administration to cats and kittens according to their weight. Each chewable flavored tablet is formulated to provide a minimum spinosad dosage of 22.5 mg/lb (50 mg/kg). Spinosad is a member of the spinosyns class of insecticides, which are non-antibacterial tetracyclic macrolides. Spinosad contains two major factors, spinosyn A and spinosyn D, derived from the naturally occurring bacterium, *Saccharopolyspora spinosa*. Spinosyn A and spinosyn D have the chemical compositions 2-[(6-deoxy-2,3,4 tri-O-methyl- α -L-mannopyranosyl)oxy]-13- [[5 (dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]- 9 ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16btetradecahydro- 14-methyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione and 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy] 13-[[5-(dimethylamino) tetrahydro-6-methyl-2H-pyran-2 yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b tetradecahydro-4,14-dimethyl- 1H-as-indaceno[3,2 d]oxacyclododecin-7,15-dione, respectively.

Indications:

COMFORTIS kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), for one month, on cats and kittens 14 weeks of age and older and two pounds of body weight or greater.

Dosage and Administration:

COMFORTIS is given orally once a month, at the minimum dosage of 22.5 mg/lb (50 mg/kg).

Do not use the dosing schedule below when administering COMFORTIS to dogs, as it can result in an overdose.

Dosage Schedule:

Body Weight	Spinosad Per Tablet (mg)	Tablets Administered
2 to 4 lbs	90	One
4.1 to 6 lbs	140	One
6.1 to 12 lbs	270	One
12.1 to 24* lbs	560	One

*Cats over 24 lbs should be administered the appropriate combination of tablets.

Administer COMFORTIS with food for maximum effectiveness.

COMFORTIS is a chewable tablet that can be consumed by cats when offered by the owner just prior to

or after feeding. Alternatively, COMFORTIS may be offered in food or administered like other tablet medications. COMFORTIS should be administered at monthly intervals.

If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.

Treatment with COMFORTIS may begin at any time of the year, preferably starting one month before fleas become active and continuing monthly through the end of flea season. In areas where fleas are common year-round, monthly treatment with COMFORTIS should continue the entire year without interruption.

To minimize the likelihood of flea reinfestations, it is important to treat all animals within a household with an approved flea protection product.

Contraindications:

There are no known contraindications for the use of COMFORTIS.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Precautions:

Use with caution with concomitant extra-label use of ivermectin (see ADVERSE REACTIONS).

The safe use of COMFORTIS in breeding, pregnant, or lactating cats has not been evaluated.

Adverse Reactions:

In a well-controlled US field study, which included a total of 211 cats (139 treated with COMFORTIS and 72 treated with an active topical control once a month for 3 treatments), no serious adverse reactions were attributed to the administration of COMFORTIS.

Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence > 1% within any of the 3 months of observations are presented in the following table. The most frequently reported adverse reaction in cats was vomiting.

Percentage of Cats (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	COMFORTIS (n=139)	Active Topical Control (n=72)	COMFORTIS (n=135)	Active Topical Control (n=69)	COMFORTIS (n=132)	Active Topical Control (n=67)
Vomiting	14.4	1.4	14.8	1.4	13.6	4.5
Lethargy	3.6	0.0	0.7	0.0	1.5	1.5
Anorexia	2.2	0.0	0.7	0.0	2.3	1.5
Weight Loss	1.4	0.0	0.0	0.0	3.0	0.0
Diarrhea	1.4	1.4	0.7	2.9	2.3	1.5

Over the 3-month (3-dose) study, vomiting occurred on the day of or the day after at least one dose in 28.1% (39/139) of the cats treated with COMFORTIS and in 2.8% (2/72) of the cats treated with the active topical control. Three of the 139 cats treated with COMFORTIS vomited on the day of or the day after all three doses.

Two cats that received extra-label topical otic ivermectin on Day -1 of the field study developed

lethargy on Day 1 after COMFORTIS administration on Day 0.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

Mode of Action:

The primary target of action of COMFORTIS in insects is an activation of nicotinic acetylcholine receptors (nAChRs). Spinosad does not interact with known binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. Insects treated with spinosad show involuntary muscle contractions and tremors resulting from activation of motor neurons. Prolonged spinosad-induced hyperexcitation results in prostration, paralysis, and flea death. The selective toxicity of spinosad between insects and vertebrates may be conferred by the differential sensitivity of the insect versus vertebrate nAChRs.

Effectiveness:

In a well-controlled laboratory study, COMFORTIS began to kill fleas 30 minutes after administration and demonstrated 98% effectiveness within 4 hours. COMFORTIS kills fleas before they can lay eggs. In a separate well-controlled laboratory study, COMFORTIS demonstrated 100% effectiveness on the first day following treatment and >90% effectiveness on Day 30.

If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment.

In a field study conducted in households with existing flea infestations, flea count reductions of 97.5% were observed one month after the first treatment and 99.3% after three monthly treatments with COMFORTIS. Cats with pre-existing signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermitis, and pruritus as a direct result of eliminating the fleas.

Animal Safety:

In a margin of safety study, COMFORTIS was administered orally to 14-week-old kittens at 1X, 3X, and 5X the upper half (75 – 100 mg/kg) of the therapeutic dose band for six monthly dosing intervals 28 days apart. Vomiting was observed across all groups, but was seen with greater frequency in cats in the treated groups; it did not increase with increasing doses. Loose stool was observed in all but the 3X treatment group. Food consumption was decreased in the 5X female cats. COMFORTIS was not associated with clinically significant changes in hematology, clinical chemistry, coagulation, or urinalysis parameters. Cats administered COMFORTIS once monthly for 6 months in the 3X and 5X dose groups demonstrated cytoplasmic vacuolation, consistent with phospholipidosis, in the liver, lung, and adrenal gland. The long term effects of phospholipidosis are unknown. The administration of COMFORTIS was not associated with any clinically significant, gross necropsy or histopathological changes.

In a well-controlled field study, COMFORTIS was administered safely in conjunction with other frequently used veterinary products, including tapeworm anthelmintics, antibiotics, and an approved heartworm preventative containing ivermectin. Hematology and clinical chemistry values were compared pre- and post-study and were unremarkable.

Storage Information:

Store at 20 to 25°C (68 to 77°F), excursions permitted between 15 to 30°C (59 to 86°F).

How Supplied:

COMFORTIS is available in four tablet sizes for use in cats: 90, 140, 270 or 560 mg. Each tablet size is available in color-coded packages of 6 tablets.

COMFORTIS®-Dogs

(spinosad)

Chewable Tablets

For information on cats, see reverse side.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

COMFORTIS (spinosad) is available in six sizes of chewable flavored tablets for oral administration to dogs and puppies according to their weight. Each chewable tablet is formulated to provide a minimum spinosad dosage of 13.5 mg/lb (30 mg/kg). Spinosad is a member of the spinosyns class of insecticides, which are non-antibacterial tetracyclic macrolides. Spinosad contains two major factors, spinosyn A and spinosyn D, derived from the naturally occurring bacterium, *Saccharopolyspora spinosa*. Spinosyn A and spinosyn D have the chemical compositions 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L mannopyranosyl)oxy]-13-[[5-dimethylamino)- tetrahydro-6 methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b, 6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl- 1H-as Indaceno[3,2-d]oxacyclododecin-7, 15-dione and 2-[(6-deoxy 2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]- 13-[[5 dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl] oxy]-9 ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 16b tetradecahydro-4,14-dimethyl-1H-as-Indaceno[3,2-d] oxacyclododecin-7,15-dione, respectively.

Indications:

COMFORTIS kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*) for one month, on dogs and puppies 14 weeks of age and older and 3.3 pounds of body weight or greater.

Dosage and Administration:

COMFORTIS is given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg).

Do not use the dosing schedule below when administering COMFORTIS to cats, as it can result in an underdosage.

Dosage Schedule:

Body Weight	Spinosad Per Tablet (mg)	Tablets Administered
3.3-4.9 lbs	90	One
5 to 10 lbs	140	One
10.1 to 20 lbs	270	One
20.1 to 40 lbs	560	One
40.1 to 60 lbs	810	One
60.1 to 120* lbs	1620	One

* Dogs over 120 lbs should be administered the appropriate combination of tablets.

Administer COMFORTIS with food for maximum effectiveness.

COMFORTIS is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, COMFORTIS may be offered in food or administered like other tablet medications. COMFORTIS should be administered at monthly intervals. If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.

Treatment with COMFORTIS may begin at any time of the year, preferably starting one month before fleas become active and continuing monthly through the end of flea season. In areas where fleas are common year-round, monthly treatment with COMFORTIS should continue the entire year without interruption.

To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product.

Contraindications:

There are no known contraindications for the use of COMFORTIS.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Serious adverse reactions have been reported following concomitant extra-label use of ivermectin with COMFORTIS (see **POST APPROVAL EXPERIENCE**).

Precautions:

COMFORTIS is for use in dogs and puppies 14 weeks of age and older (see **ANIMAL SAFETY**).

Use with caution in breeding females (see **ANIMAL SAFETY**). Use with caution in dogs with pre-existing epilepsy (see **ADVERSE REACTIONS**). The safe use of COMFORTIS in breeding males has not been evaluated.

Adverse Reactions:

In a well-controlled US field study, which included a total of 470 dogs (330 dogs treated with COMFORTIS and 140 dogs treated with an active control), no serious adverse reactions were observed with COMFORTIS. All reactions were regarded as mild and did not result in any dog being removed from the study.

Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence > 1% within any of the 3 months of observation are presented in the following table. The most frequently reported adverse reaction in dogs in the COMFORTIS and active control groups was vomiting. The occurrence of vomiting, most commonly within 48 hours after treatment, decreased with repeated doses of COMFORTIS. Percentage of Dogs (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	COMFORTIS Chewable Tablets (N=330)	Active Topical Control (n=139 ^a)	COMFORTIS Chewable Tablets (N=282)	Active Topical Control (n=124)	COMFORTIS Chewable Tablets (N=260)	Active Topical Control (n=125)
Vomiting	12.7	12.2	7.8	3.2	5.8	4.8
Decreased Appetite	9.1	5.0	2.8	1.6	1.9	0.8

Lethargy	7.6	5.0	3.5	4.0	1.2	0.8
Diarrhea	6.7	5.0	4.3	0.8	1.2	0.0
Cough	3.9	5.0	0.4	2.4	0.0	0.0
Polydipsia	2.4	1.4	0.7	0.0	0.4	0.0
Vocalization	1.8	0.0	0.4	0.0	0.4	0.0
Increased Appetite	1.5	0.0	0.4	0.8	0.4	0.0
Erythema	1.5	0.0	0.4	0.0	0.4	0.0
Hyperactivity	1.2	1.4	0.0	0.0	0.4	0.0
Excessive Salivation	1.2	0.0	0.4	0.0	0.0	0.0

^a This number (n=139) is less than the total number of dogs in the safety population for the active control group (n=140) because one dog joined the study late and was only dosed at Month 3.

In US and European field studies, no dogs experienced seizures when dosed with COMFORTIS at the therapeutic dose range of 13.5-27.3 mg/lb (30-60 mg/kg), including 4 dogs with pre-existing epilepsy. Four epileptic dogs that received higher than the maximum recommended dose of 27.3 mg/lb (60 mg/kg) experienced at least one seizure within the week following the second dose of COMFORTIS, but no seizures following the first and third doses. The cause of the seizures observed in the field studies could not be determined.

Post Approval Experience (June 2009):

The following adverse reactions are based on post-approval adverse drug event reporting. The adverse reactions are listed in decreasing order of frequency: *vomiting, depression/lethargy, anorexia, ataxia, diarrhea, pruritus, trembling, hypersalivation and seizures.*

Following concomitant extra-label use of ivermectin with COMFORTIS, some dogs have experienced the following clinical signs: *trembling/twitching, salivation/drooling, seizures, ataxia, mydriasis, blindness and disorientation.*

Post approval experience continues to support the safety of COMFORTIS when used concurrently with heartworm preventatives according to label directions.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

Mode of Action:

The primary target of action of COMFORTIS in insects is an activation of nicotinic acetylcholine receptors (nAChRs). Spinosad does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. Insects treated with spinosad show involuntary muscle contractions and tremors resulting from activation of motor neurons. Prolonged spinosad-induced hyperexcitation results in prostration, paralysis, and flea death. The selective toxicity of spinosad between insects and vertebrates may be conferred by the differential sensitivity of the insect versus vertebrate nAChRs.

Effectiveness:

In a well-controlled laboratory study, COMFORTIS began to kill fleas 30 minutes after administration and demonstrated 100% effectiveness within 4 hours. COMFORTIS kill fleas before they can lay eggs. If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment. In field studies conducted in households with existing flea infestations of varying severity, flea reductions of

98.0% to 99.8% were observed over the course of 3 monthly treatments with COMFORTIS. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermitis and pruritus as a direct result of eliminating the fleas.

Animal Safety:

COMFORTIS was tested in pure and mixed breeds of healthy dogs in well-controlled clinical and laboratory studies. No dogs were withdrawn from the field studies due to treatment-related adverse reactions.

In a dose tolerance study, COMFORTIS was administered orally to adult Beagle dogs at average doses of up to 100 mg/kg once daily for 10 consecutive days (16.7 times the maximum recommended monthly dose). Vomiting was seen in 5 of 6 treated dogs during the first 6 days of treatment, usually within 2.5 hours of dosing. Treated females lost weight early in the treatment period, but their weights were similar to control dogs by the end of the 24-day study. COMFORTIS was not associated with any clinically significant changes in hematology, blood coagulation or urinalysis parameters; however, mild elevations in ALT occurred in all dogs treated with COMFORTIS. By day 24, ALT values had returned to near baseline levels. Phospholipidosis (vacuolation) of the lymphoid tissue was seen in all dogs treated with COMFORTIS, the long-term effects of which are unknown.

In a margin of safety study, COMFORTIS was administered orally to 6-week-old Beagle puppies at average doses of 1.5, 4.4, and 7.4 times the maximum recommended dose at 28-day intervals over a 6-month period. Vomiting was observed across all groups, including the control. Increased vomiting was observed at elevated doses, usually within 1 hour following administration. Vomiting at all doses decreased over time and stabilized when puppies were 14 weeks of age. The average daily and total weight gains of treated dogs were smaller than control dogs and were dose dependent. COMFORTIS was not associated with clinically significant changes in hematology, clinical chemistry, coagulation or urinalysis parameters. Phospholipidosis (vacuolation) of the lymphoid tissue was seen in some dogs in the 4.4X group and all dogs in the 7.4X group. The long term effects of phospholipidosis are unknown. Treatment with COMFORTIS was not associated with any other clinically significant adverse clinical observations, gross necropsy or histopathological changes.

In a reproductive safety study, COMFORTIS was administered orally to female Beagles at 1.3 and 4.4 times the maximum recommended therapeutic dose every 28 days prior to mating, during gestation, and during a six-week lactation period. No treatment-related adverse effects were noted for conception rates in the dams, or for mortality, body temperature, necropsy, or histopathology findings for the dams or puppies. One dam from each treatment group experienced early pregnancy loss and one additional high dose dam aborted late term. The treated dams experienced more vomiting, especially at one hour post-dose, than the control dams. Puppies from dams treated at 1.3 times the maximum recommended therapeutic dose had lower body weights than puppies from control dams. Although puppy mortality between treated and control dams was not different, the puppies from the treated dams experienced more lethargy (4.4X group only), dehydration, weakness and felt cold to the touch (4.4X group only) than puppies from control dams.

A pilot study without a control group was conducted to analyze milk from three lactating dogs treated with an experimental formulation of spinosad at 1.5 times the maximum recommended dose administered at day 28 of gestation and 24 hours prior to parturition. The data demonstrated that spinosyns were excreted in the milk of these dogs. Mortality and morbidity were greatest in puppies from the dam with the highest spinosyns level in milk. The spinosad milk: reference plasma exposure ratio calculated from this study ranged from 2.2 to 3.5.

In well-controlled field studies, COMFORTIS was administered safely in conjunction with other frequently used veterinary products, such as vaccines, anthelmintics, antibiotics, steroids, flea and tick control products, anesthetics, NSAIDs, antihistamines, alternative/herbal remedies, shampoos, and prescription diets. Changes in hematology, clinical chemistry and urinalysis values were compared pre- and post-study and were unremarkable.

Storage Information:

Store at 20-25°C (68 -77°F), excursions permitted between 15 to 30°C (59 to 86°F).

How Supplied:

COMFORTIS is available in six tablet sizes for use in dogs: 90, 140, 270, 560, 810 or 1620 mg. Each tablet size is available in color-coded packages of 6 tablets.

NADA #141-277, Approved by the FDA

Manufactured for Elanco Animal Health,
A Division of Eli Lilly and Company,
Indianapolis, IN 46285

www.comfortis.com

Elanco, Comfortis and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

NDC 0986-4221-06	CA4221
NDC 0986-4222-06	CA4222
NDC 0986-4223-06	CA4223
NDC 0986-4224-06	CA4224
NDC 0986-4225-06	CA4225
NDC 0986-4227-06	CA4227

COMFORTIS®-Cats

(spinosad)

Chewable Tablets

For information on dogs, see reverse side.

Your veterinarian has chosen to prescribe COMFORTIS to meet your flea treatment and prevention needs. Controlling fleas is important to the health of your cat. Please read this leaflet, which describes the proper use of COMFORTIS to treat and prevent flea infestations. If you have any questions about this information, please consult your veterinarian. Additional information can be found at www.comfortis.com.

What is COMFORTIS?

COMFORTIS is a chewable, flavored tablet that you give to your cat to kill fleas and prevent flea infestations for one month. COMFORTIS is for monthly use in cats and kittens 14 weeks of age or older and 2 pounds of body weight or greater.

Why has my veterinarian prescribed COMFORTIS?

Your veterinarian has provided this medication to either prevent a flea infestation or to treat an existing flea infestation on your cat.

What should I discuss with my veterinarian regarding COMFORTIS for my cat?

Your veterinarian is your cat's healthcare expert and can make the best recommendation for medications for your cat. This includes the prevention and treatment of parasites such as fleas that may cause conditions that include flea allergy dermatitis, anemia, and other flea-related problems.

Key points of your discussion may include the following:

- Treatment with COMFORTIS may begin at any time of the year, preferably starting one month before fleas become active and continuing through the end of flea season. In areas where fleas may

occur year-round, monthly treatment with COMFORTIS should continue the entire year without interruption.

- If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.
- To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product.
- COMFORTIS is not for use in humans. Like all medications, keep COMFORTIS out of reach of children.
- Make sure your veterinarian is aware of all medications, including over-the-counter (OTC) medications, that you are giving to your cat.

How should I give COMFORTIS to my cat?

Give COMFORTIS with food for maximum effectiveness. COMFORTIS is a chewable tablet that can be consumed by cats when offered just prior to or just after feeding. Alternatively, COMFORTIS may be offered in food or administered like other tablet medications.

Give COMFORTIS to your cat once a month. To help you remember the monthly dosing schedule, stick-on labels are included for your calendar.

What if I give more than the prescribed amount of COMFORTIS to my cat?

COMFORTIS has been tested in many types of cats, and no severe adverse reactions have been reported. At elevated dose rates, the most severe adverse reaction observed was increased vomiting and loose stool. In the event of possible overdose, contact your veterinarian, who is the healthcare expert for your cat.

Should I restrict either my cat's activity or contact with my cat after the tablet is consumed?

Since COMFORTIS is an oral formulation, you may maintain normal activities and interactions with your cat.

How quickly will COMFORTIS kill fleas?

In a laboratory study, COMFORTIS started to kill fleas within 30 minutes and killed 100% of the fleas within 24 hours. COMFORTIS kills fleas before they can lay eggs.

Does seeing fleas on my cat mean that the treatment is not working?

COMFORTIS kills fleas before they can lay eggs when used monthly according to the label directions. Remember that all animals in the household should be treated with an approved flea product to help control the flea population.

Female fleas that are living on animals produce eggs that fall from the animal into their surroundings. These eggs hatch within a week; larvae then emerge and spin cocoons to become pupae. The entire life cycle can be completed in as little as 3 weeks, with new adult fleas emerging from the pupae to jump onto your cat. Because each female flea can lay up to 50 eggs per day, there is potential for a large build-up of eggs, larvae and pupae, resulting in a constant supply of new adults emerging in the cat's environment.

Regardless of the product used to kill the fleas, the cat can continue to be exposed to the fleas that live in the environment. If these fleas jump onto the cat, they will be killed by COMFORTIS.

If you see fleas on your cat within a month after your cat receives COMFORTIS, it is most likely that these are new fleas that have recently emerged from pupae and jumped onto the cat. These new fleas will be killed before they can produce eggs that contaminate the environment.

Is it safe to give my cat COMFORTIS?

COMFORTIS has been demonstrated to be safe in cats when used according to label directions. Safety was shown in cats and kittens 14 weeks of age and older, in multiple laboratory studies and a field study in household cats. The safe use of COMFORTIS in breeding, pregnant, or lactating cats has not been

evaluated.

What side effects might occur with COMFORTIS?

Like all medications, sometimes side effects may occur. In some cases, cats vomited after receiving COMFORTIS. If vomiting occurs within one hour of administration, redose with another full dose. Additional adverse reactions observed in studies were lethargy, decreased appetite, weight loss, and diarrhea.

Can other medications be given while my cat is taking COMFORTIS?

Yes, COMFORTIS has been given safely with a wide variety of products and medications. Your veterinarian should be made aware of all medications, including over-the-counter (OTC) medications, that you are giving to your cat. For heartworm prevention, use products that are specifically prescribed by your veterinarian.

How should COMFORTIS be stored?

Store at 68 to 77°F (20 to 25°C). Temporary periods of time outside of this range between 59 to 86°F (15 to 30°C) are permitted.

If you have questions regarding the use of this product, consult your veterinarian, your cat's healthcare expert. Additional information can be found at www.comfortis.com.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

COMFORTIS®-Dogs

(spinosad)

Chewable Tablets

For information on cats, see reverse side.

Your veterinarian has chosen to prescribe COMFORTIS to meet your flea treatment and prevention needs. Controlling fleas is very important to the health of your dog. Please read this leaflet, which describes the use of COMFORTIS to treat and prevent flea infestations. If you have any questions about this information, please consult your veterinarian. Additional information can be found at www.comfortis.com.

What is COMFORTIS?

COMFORTIS is a chewable, flavored tablet that you give to your dog to kill fleas and prevent flea infestations for one month. COMFORTIS are for monthly use in dogs and puppies 14 weeks of age or older and 3.3 pounds of body weight or greater.

Why has my veterinarian prescribed COMFORTIS?

Your veterinarian has provided this medication to either prevent a flea infestation or to treat an existing infestation on your dog.

What should I discuss with my veterinarian regarding COMFORTIS for my dog?

Your veterinarian is your dog's healthcare expert and can make the best recommendation for medications for your dog. This includes the prevention and treatment of parasites such as fleas that may cause conditions that include flea allergy dermatitis, anemia, and other flea-related problems. Key points of your discussion may include the following:

- Treatment with COMFORTIS may begin at any time of the year, preferably starting one month before fleas become active and continuing through the end of flea season. In areas where fleas may occur year-round, monthly treatment with COMFORTIS should continue the entire year without interruption.

- If a dose is missed, administer COMFORTIS with food and resume a monthly dosing schedule.
- To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product.
- COMFORTIS is not for use in humans. Like all medications, keep COMFORTIS out of reach of children.

How should I give COMFORTIS to my dog?

Give COMFORTIS with food for maximum effectiveness.

COMFORTIS is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, COMFORTIS may be offered in food or administered like other tablet medications.

Give COMFORTIS to your dog once a month. To help you remember the monthly dosing schedule, stick-on labels are included for your calendar.

What if I give more than the prescribed amount of COMFORTIS to my dog?

COMFORTIS has been tested in many types of dogs, and no severe adverse reactions have been reported. At elevated dose rates, the most severe adverse reaction observed was increased vomiting. In the event of a possible overdose, contact your veterinarian, who is the healthcare expert for your dog.

Should I restrict either my dog's activity or contact with my dog after the tablet is consumed?

Since COMFORTIS is an oral formulation, you may maintain normal activities and interactions with your dog.

How quickly will COMFORTIS kill fleas?

In a laboratory study, COMFORTIS started to kill fleas within 30 minutes and killed 100% of the fleas within 4 hours. COMFORTIS kills fleas before they can lay eggs.

Does seeing fleas on my dog mean that the flea treatment is not working?

COMFORTIS kills fleas before they can lay eggs when used monthly according to the label directions. Remember that all animals in the household should be treated with an approved flea product to help control the flea population.

Female fleas that are living on animals produce eggs that fall from the animal into their surroundings. These eggs hatch within a week; larvae then emerge and spin cocoons to become pupae. The entire life cycle can be completed in as little as 3 weeks, with new adult fleas emerging from the pupae to jump onto your dog. Because each female flea can lay up to 50 eggs per day there is potential for a large build-up of eggs, larvae and pupae, resulting in a constant supply of new adults emerging in the dog's environment.

Regardless of the product used to kill the fleas, the dog can continue to be exposed to the fleas that live in the environment. When these fleas jump onto the dog, they will be quickly killed by COMFORTIS.

If you see fleas on your dog within a month after your dog receives COMFORTIS, it is most likely that these are new fleas that have very recently emerged from pupae and jumped onto the dog. These new fleas will quickly be killed before they can produce eggs that contaminate the environment.

Is it safe to give my dog COMFORTIS?

COMFORTIS has been demonstrated to be safe in pure and mixed breeds of healthy dogs when used according to label directions. Safety was shown in puppies 14 weeks of age and older and adult dogs in both laboratory studies and clinical field studies. You should discuss the use of COMFORTIS with your veterinarian prior to use if your dog has a history of epilepsy (seizures).

Is it safe to give my breeding dogs COMFORTIS?

Use with caution in breeding females. You should discuss the use of COMFORTIS with your veterinarian prior to use in breeding females. Safe use of COMFORTIS in male dogs intended for breeding has not been evaluated.

What side effects might occur with COMFORTIS?

Like all medications, sometimes side effects may occur. In some cases, dogs vomited after receiving COMFORTIS. If vomiting occurs within an hour of administration, redose with another full dose. During clinical studies, no severe or prolonged vomiting occurred. Additional adverse reactions observed in the clinical studies were decreased appetite, lethargy or decreased activity, diarrhea, cough, increased thirst, vocalization, increased appetite, redness of the skin, hyperactivity and excessive salivation. These reactions were regarded as mild and did not result in any dog being removed from the studies.

Since the introduction of COMFORTIS, additional side effects reported are incoordination, itching, trembling and seizures.

Can other medications be given while my dog is taking COMFORTIS?

Yes, COMFORTIS has been given safely with a wide variety of products and medications. Your veterinarian should be made aware of all products that you administered and/or intend to administer to your dog. For heartworm prevention, use products that are specifically prescribed by your veterinarian.

How should COMFORTIS be stored?

Store at 68-77°F (20-25°C). Temporary periods of time outside of this range between 59-86°F (15-30°C) are permitted.

If you have questions regarding the use of this product, consult your veterinarian, your dog's healthcare expert. Additional information can be found at www.comfortis.com.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

Elanco, Comfortis and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

NDC 0986-4221-06	CA4221
NDC 0986-4222-06	CA4222
NDC 0986-4223-06	CA4223
NDC 0986-4224-06	CA4224
NDC 0986-4225-06	CA4225
NDC 0986-4227-06	CA4227

Principal Display Panel - 90 mg Blister Label

Comfortis (spinosad)

For Dogs, Puppies, Cats and Kittens

14 weeks of age and older

3.3-4.9 lb dogs and 2-4 lb cats

90 mg

(Give with a meal)

- - - - -

Puncture Here

Manufactured for Elanco Animal Health,
Indianapolis, IN 46285

Lot#

Exp.



Principal Display Panel - 90 mg Carton Label

FOR CATS

2-4 lbs

FOR DOGS

3.3-4.9 lbs

6 CHEWABLE TABLETS

90 mg

KILLS FLEAS

FAST ACTING

ONCE A MONTH

Comfortis[®] (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™



138168
CA4221

Sep 2014
NDC 0986-4221-06

For complete product information, see package insert. Questions? Consult your veterinarian (your dog or cat's health care expert) or visit www.comfortis.com. For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/animal/veterinary/safety/health>

JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----

DOSE TRACKING CHART FOR:

DOSE AND ADMINISTRATION: Comfortis chewable tablets are given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg) for dogs, and 22.5 mg/lb (50 mg/kg) for cats. Administer Comfortis chewable tablets with food for maximum effectiveness. Store at 20-25°C (68-77°F), excursions permitted between 15-30°C (59-86°F).

- Starts killing fleas in 30 minutes
- Kills fleas before they can lay eggs
- Give with a meal

www.comfortis.com
Indianapolis, IN 46285

Manufactured for Elanco Animal Health, A Division of Eli Lilly and Company, trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates. Elanco, Comfortis and the diagonal bar are extra-label use of Ivermectin with spinosad. reactions have been reported following concomitant drugs out of the reach of children. Serious adverse Warnings: Not for human use. Keep this and all on dogs and cats 14 weeks of age and older. infestations (*Ctenocephalides felis*), for one month, indicated for the prevention and treatment of flea

Comfortis chewable tablets kill fleas and are (spinosad)
Comfortis

6 CHEWABLE TABLETS 90 mg
FOR DOGS 3.3-4.9 lbs
FOR CATS 2-4 lbs

Comfortis
(spinosad)

FOR CATS 2-4 lbs
FOR DOGS 3.3-4.9 lbs

6 CHEWABLE TABLETS 90 mg



FOR CATS 2-4 lbs



FOR DOGS 3.3-4.9 lbs

6 CHEWABLE TABLETS 90 mg



KILLS FLEAS FAST ACTING ONCE A MONTH

FOR CATS 2-4 lbs
FOR DOGS 3.3-4.9 lbs
6 CHEWABLE TABLETS 90 mg



Comfortis (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

- Starts killing fleas in 30 mins.
- Kills fleas before they can lay eggs
- Give with a meal

APPROVED BY FDA

NADA 141-277



Comfortis
(spinosad)



Comfortis
(spinosad)

LOT NO:
EXP.

Principal Display Panel - 90 mg Box Label

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

**KILLS FLEAS
FAST ACTING
ONCE A MONTH**

www.comfortis.com

Starts killing fleas in 30 mins.
Kills fleas before they can lay eggs
Give with a meal

Elanco™



Principal Display Panel - 140 mg Blister Label

Comfortis (spinosad)

For Dogs, Puppies, Cats and Kittens
14 weeks of age and older

5-10 lb dogs and 4.1-6 lb cats

140 mg

(Give with a meal)

Puncture Here

Manufactured for Elanco Animal Health,

Exp.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™

Principal Display Panel - 140 mg Box Label

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS

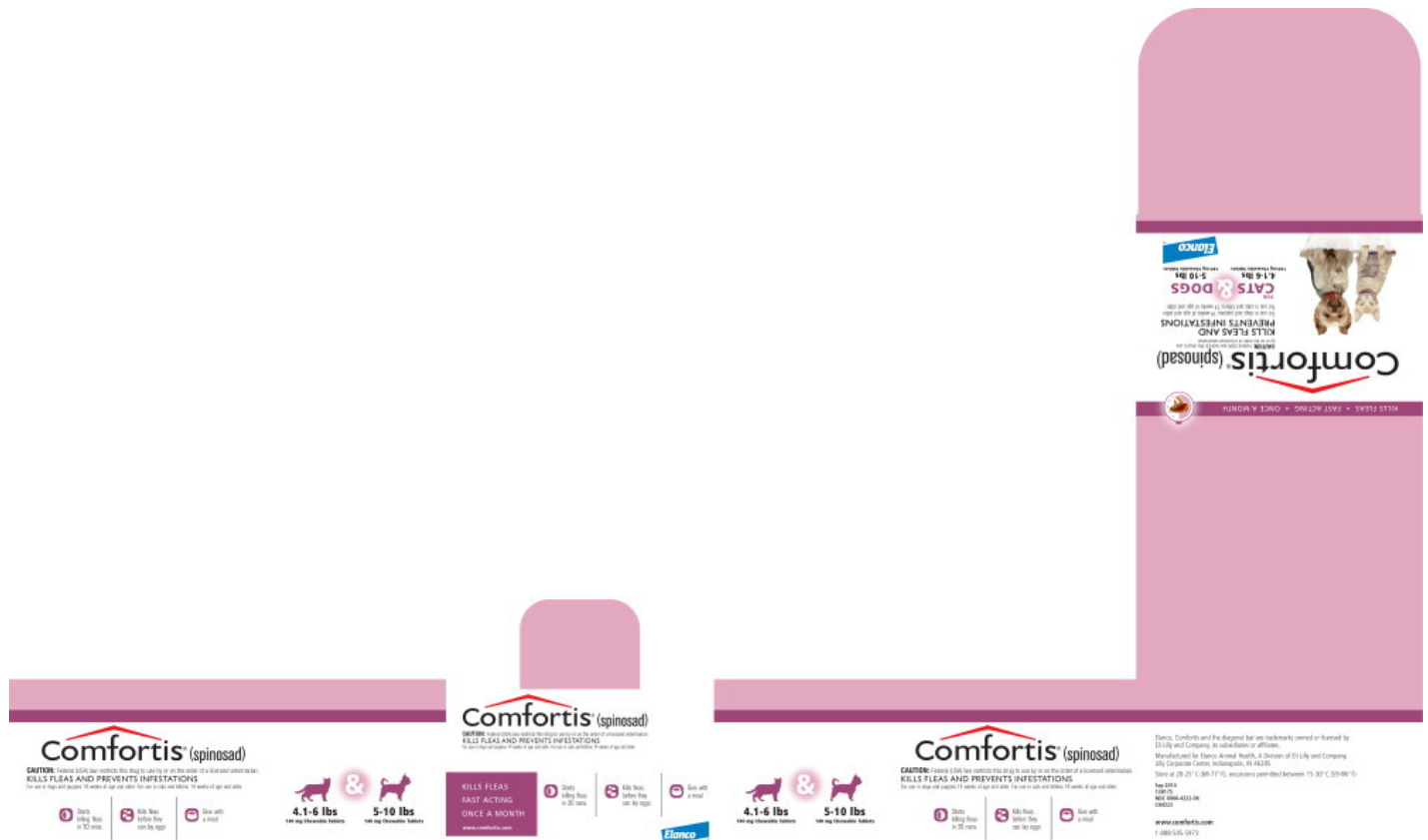
For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

**KILLS FLEAS
FAST ACTING
ONCE A MONTH**

www.comfortis.com

Starts killing fleas in 30 mins.
Kills fleas before they can lay eggs
Give with a meal

Elanco™



Principal Display Panel - 270 mg Blister Label

Comfortis (spinosad)

For Dogs, Puppies, Cats and Kittens
14 weeks of age and older

10.1-20 lb dogs and 6.1-12 lb cats

270 mg

(Give with a meal)

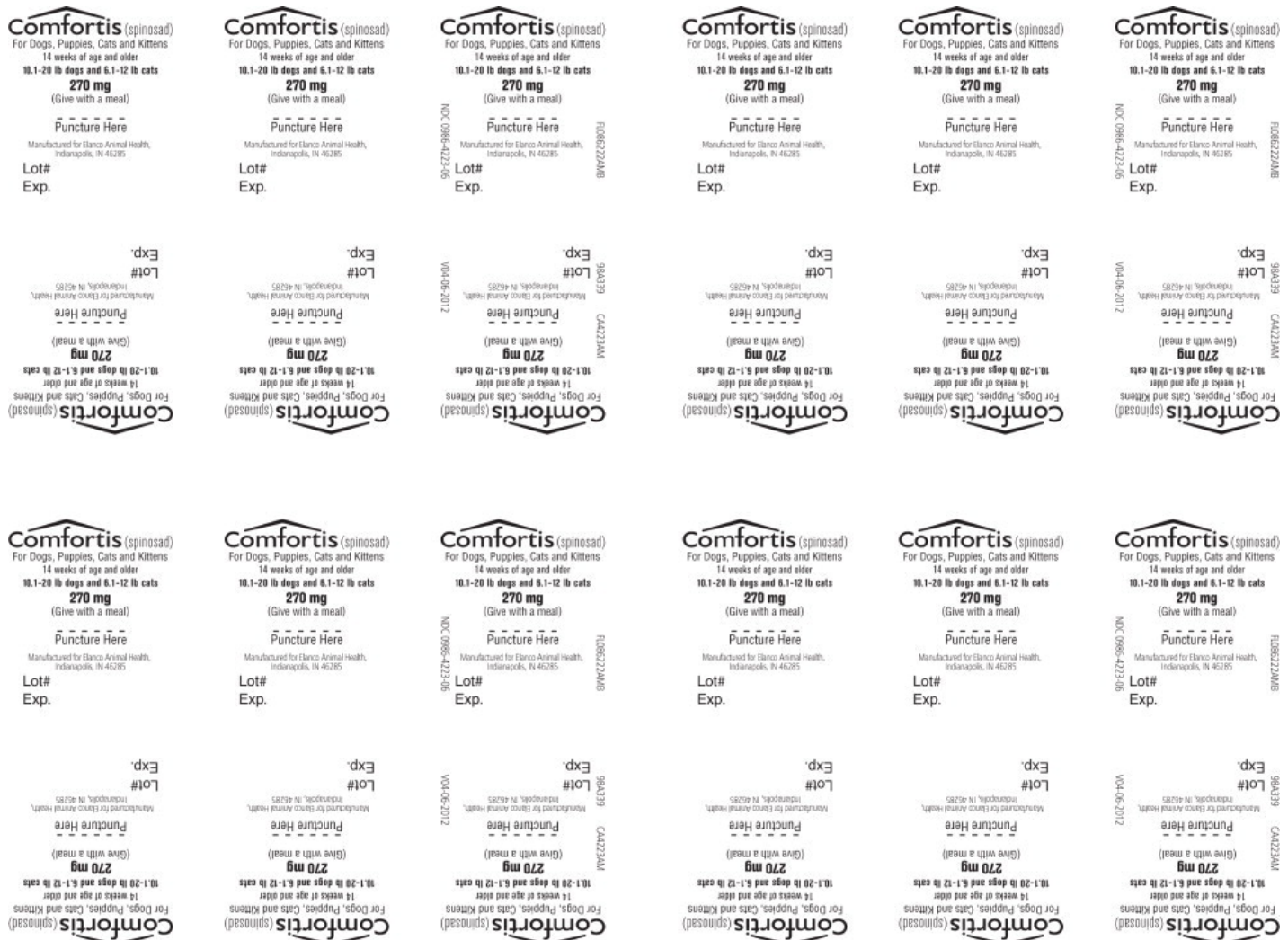
Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#

Exp.



Principal Display Panel - 270 mg Carton Label

FOR CATS

6.1-12 lbs

FOR DOGS

10.1-20 lbs

6 CHEWABLE TABLETS

270 mg

KILLS FLEAS

FAST ACTING

ONCE A MONTH

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™

Comfortis® (spinosad)

- Starts killing fleas in 30 minutes
- Kills fleas before they can lay eggs
- Give with a meal

Comfortis®
(spinosad)

**KILLS FLEAS
FAST ACTING
ONCE A MONTH**

Comfortis®
(spinosad)

1 3 B 1 7 0

Comfortis® (spinosad)

 Give with a meal



Comfortis®
(spinosad)

3 09864 22306 9

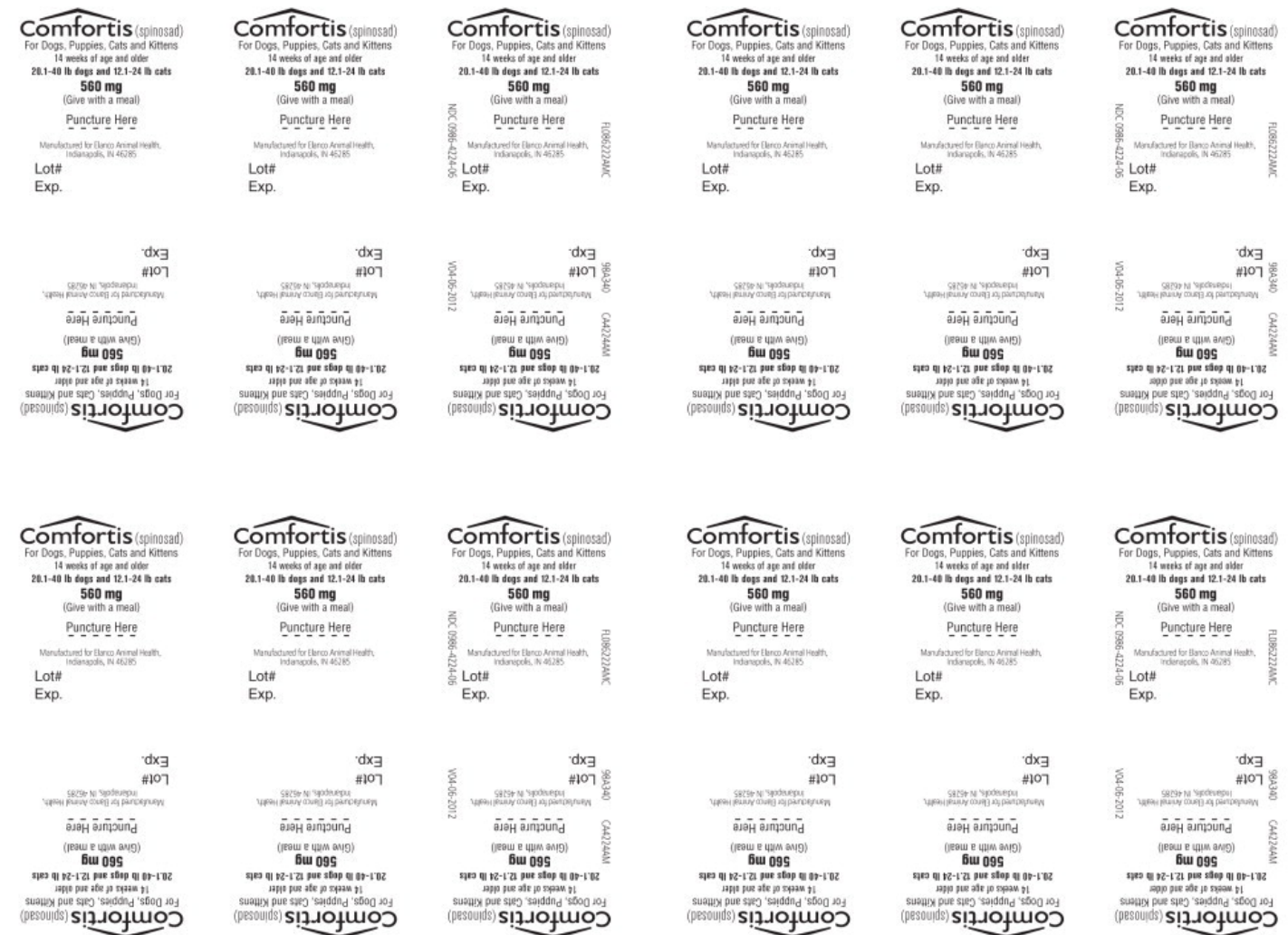
LOT NO:
EXP.



Indianapolis, IN 46285

Lot#

Exp.



Principal Display Panel - 560 mg Carton Label

FOR CATS

12.1-24 lbs

FOR DOGS

20.1-40 lbs

6 CHEWABLE TABLETS

560 mg

KILLS FLEAS

FAST ACTING

ONCE A MONTH

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™

Comfortis
(spinosad)

3 09864 22406 6

Principal Display Panel – 560 mg Box Label

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older. For use in cats and kittens 14 weeks of age and older.

KILLS FLEAS
FAST ACTING
ONCE A MONTH

www.comfortis.com

Starts killing fleas in 30 mins.
Kills fleas before they can lay eggs
Give with a meal

Elanco™



Principal Display Panel - 810 mg Blister Label

Comfortis (spinosad)

For Dogs and Puppies
14 weeks of age and older
40.1-60 lb **810** mg
(Give with a meal)

Manufactured for Elanco Animal Health,
Indianapolis, IN 46285
Lot#
Exp.



Principal Display Panel - 810 mg Carton Label

FOR DOGS

40.1-60 lbs

6 CHEWABLE TABLETS

810 mg

KILLS FLEAS

FAST ACTING

ONCE A MONTH

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™

Elanco

13B172
CA4225

Sep 2014
NDC 0986-4225-06

For complete product information, see package insert. Questions? Consult your veterinarian (your dog's health care expert) or visit www.comfortis.com. For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC

DOSE TRACKING CHART FOR:

Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F).

DOSE AND ADMINISTRATION: Comfortis chewable tablets are given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg). Administer Comfortis chewable tablets with food for maximum effectiveness.

- Starts killing fleas in 30 minutes
- Kills fleas before they can lay eggs
- Give with a meal

www.comfortis.com
Indianapolis, IN 46285

Manufactured for Elanco Animal Health, A Division of Eli Lilly and Company, Eli Lilly and Company, its subsidiaries or affiliates. Elanco, Comfortis and the diagonal bar are trademarks owned or licensed by Elanco. Comfortis and the diagonal bar are extra-label use of Ivermectin with spinosad. Reactions have been reported following concomitant use of ivermectin with spinosad. Warnings: Not for human use. Keep this and all drugs out of the reach of children. Serious adverse reactions have been reported following concomitant use of ivermectin with spinosad. Indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), for one month, on dogs 14 weeks of age and older.

Comfortis® (spinosad)

**FOR DOGS
40.1-60 lbs**
6 CHEWABLE TABLETS 810 mg

**FOR DOGS
40.1-60 lbs**
6 CHEWABLE TABLETS 810 mg



**FOR DOGS
40.1-60 lbs**

6 CHEWABLE TABLETS 810 mg



KILLS FLEAS FAST ACTING ONCE A MONTH

Comfortis® (spinosad)



**FOR DOGS
40.1-60 lbs**
6 CHEWABLE TABLETS 810 mg

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older.

- Starts killing fleas in 30 mins.
- Kills fleas before they can lay eggs
- Give with a meal

APPROVED BY FDA

NADA 141-277

Elanco

Comfortis® (spinosad)



LOT NO:
EXP.

Principal Display Panel – 810 mg Box Label

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older.

KILLS FLEAS

FAST ACTING

ONCE A MONTH

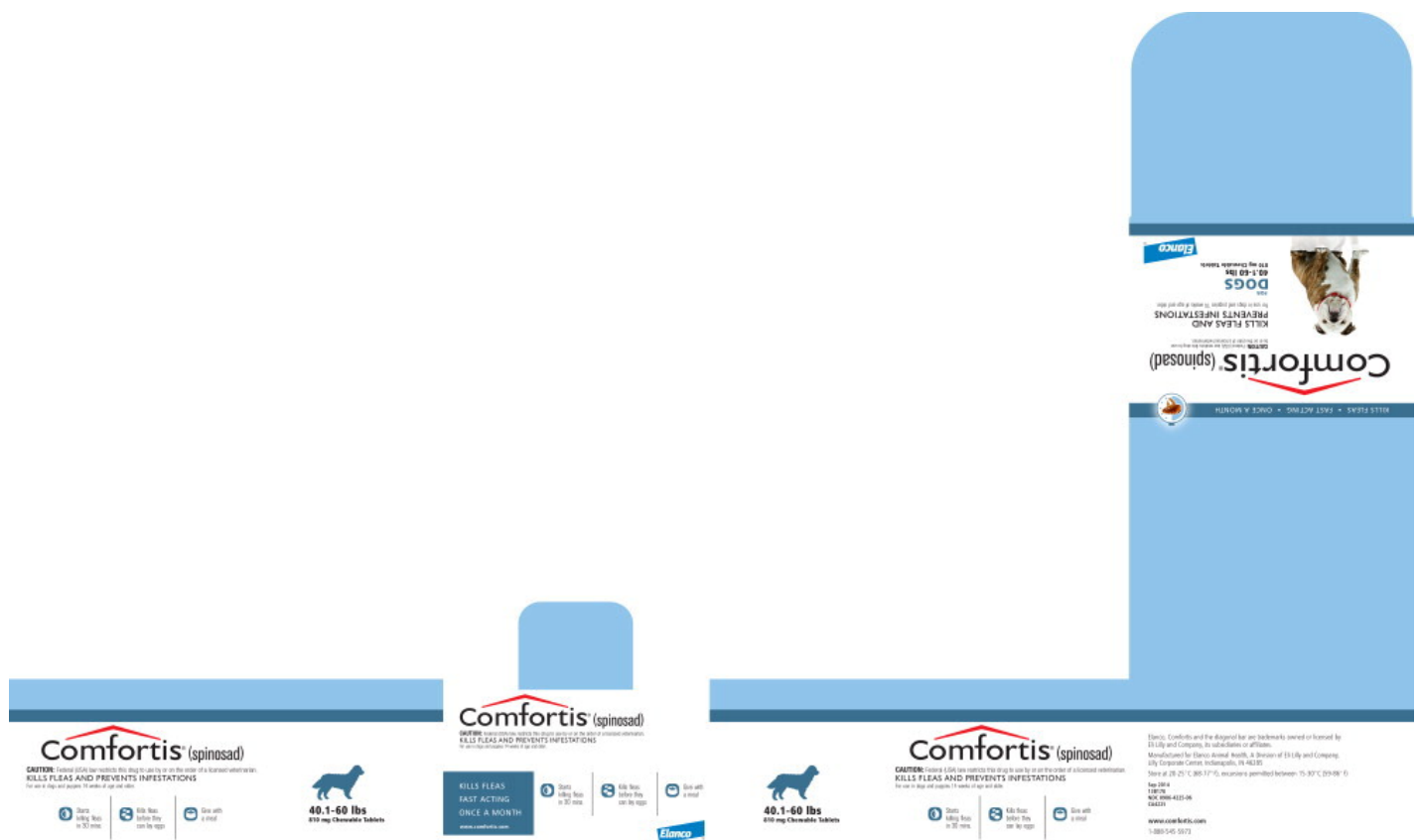
www.comfortis.com

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

Elanco™



Principal Display Panel - 1620 mg Blister Label

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

60.1-120 lb **1620 mg**

(Give with a meal)

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Puncture Here

Lot#
Exp.



Principal Display Panel - 1620 mg Carton Label

FOR DOGS
60.1-120 lbs

6 CHEWABLE TABLETS
1620 mg

KILLS FLEAS
FAST ACTING
ONCE A MONTH

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older.

Starts killing fleas in 30 mins.

Kills fleas before they can lay eggs

Give with a meal

APPROVED BY FDA NADA 141-277 *Elanco*™

Elanco

13B173
CA4227

Sep 2014
NDC 0986-4227-06

For complete product information, see package insert. Questions? Consult your veterinarian (your dog's health care expert) or visit www.comfortis.com. For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----

DOSE TRACKING CHART FOR:

Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F).

DOSE AND ADMINISTRATION: Comfortis chewable tablets are given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg). Administer Comfortis chewable tablets with food for maximum effectiveness.

-  Starts killing fleas in 30 minutes
-  Kills fleas before they can lay eggs
-  Give with a meal

Comfortis® (spinosad)
Comfortis chewable tablets kill fleas and are indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), for one month, on dogs 14 weeks of age and older.
Warning: Not for human use. Keep this and all drugs out of the reach of children. Serious adverse reactions have been reported following concomitant extra-label use of Ivermectin with spinosad.
Elanco, Comfortis and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates. Manufactured for Elanco Animal Health, Indianapolis, IN 46285
www.comfortis.com

**FOR DOGS
60.1-120 lbs**
6 CHEWABLE TABLETS 1620 mg

**FOR DOGS
60.1-120 lbs**
6 CHEWABLE TABLETS 1620 mg



**FOR DOGS
60.1-120 lbs**

6 CHEWABLE TABLETS 1620 mg



**KILLS FLEAS
FAST ACTING
ONCE A MONTH**

**Comfortis®
(spinosad)**



**FOR DOGS
60.1-120 lbs**
6 CHEWABLE TABLETS 1620 mg

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older.

-  Starts killing fleas in 30 mins.
-  Kills fleas before they can lay eggs
-  Give with a meal

APPROVED BY FDA

NADA 141-277

Elanco

**Comfortis®
(spinosad)**

3 0 0 8 6 4 2 2 7 0 6 7

1 3 B 1 7 3

**Comfortis®
(spinosad)**

LOT NO:
EXP.

Principal Display Panel – 1620 mg Box Label

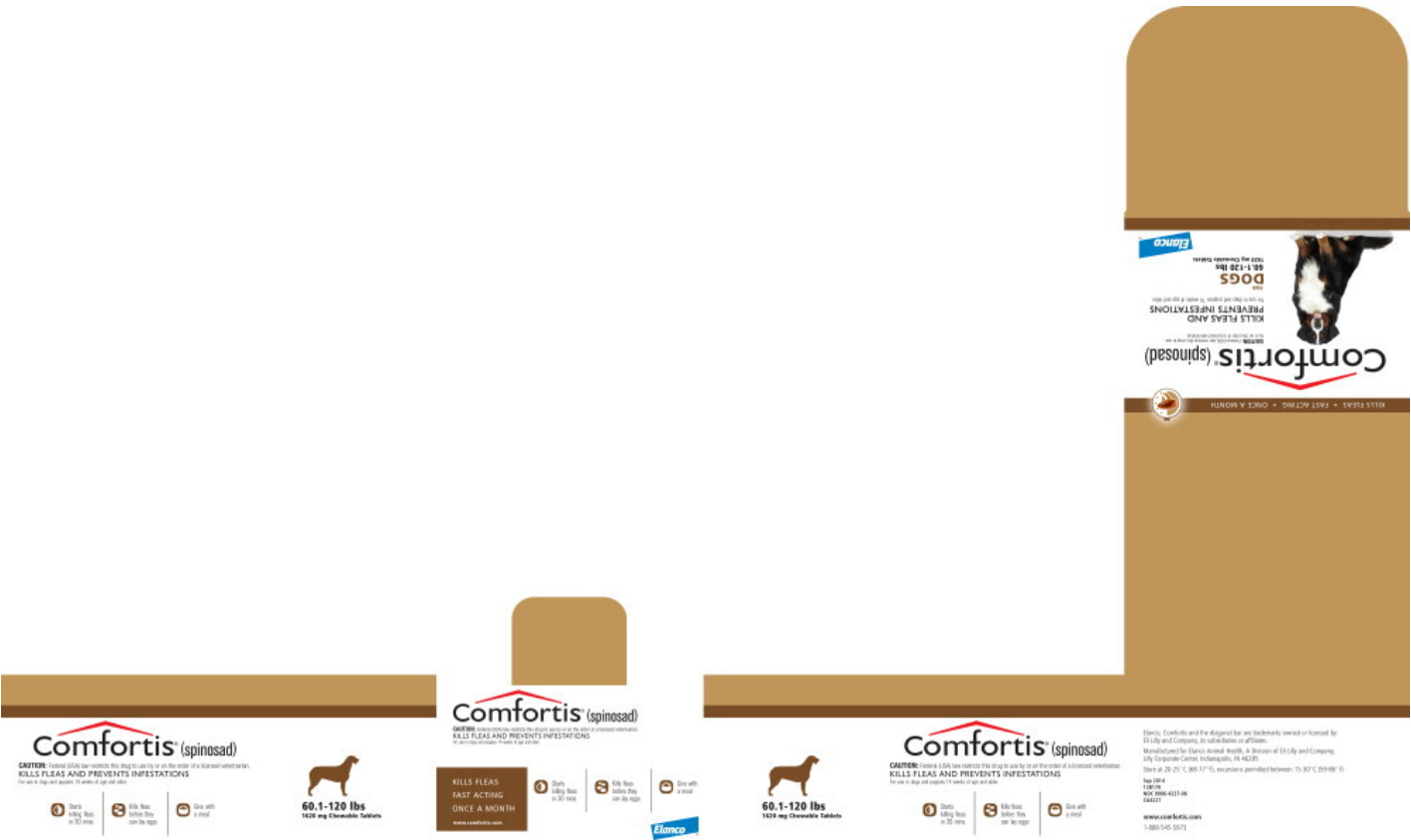
Comfortis® (spinosad)
CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS
For use in dogs and puppies 14 weeks of age and older.

KILLS FLEAS
FAST ACTING
ONCE A MONTH

www.comfortis.com

Starts killing fleas in 30 mins.
Kills fleas before they can lay eggs
Give with a meal

Elanco™



COMFORTIS

spinosad tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4221
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)	SPINOSAD	90 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor	MEAT (MEAT)	Imprint Code	4221
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4221-10	10 in 1 BOX		
1	NDC:0986-4221-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141277	10/18/2012	

COMFORTIS

spinosad tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4222
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)	SPINOSAD	140 mg

Inactive Ingredients				
Ingredient Name			Strength	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
WATER (UNII: 059QF0KO0R)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
Product Characteristics				
Color	brown (brown)	Score	no score	
Shape	ROUND (ROUND)	Size	9mm	
Flavor	MEAT (MEAT)	Imprint Code	4222	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4222-10	10 in 1 BOX		
1	NDC:0986-4222-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA141277		10/18/2012	

COMFORTIS

spinosad tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4223
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)		SPINOSAD	270 mg
Inactive Ingredients			
Ingredient Name			Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)			

SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor	MEAT (MEAT)	Imprint Code	4223
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4223-10	10 in 1 BOX		
1	NDC:0986-4223-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141277	10/18/2012	

COMFORTIS

spinosad tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4224
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)	SPINOSAD	560 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics			
Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	16 mm
Flavor	MEAT (MEAT)	Imprint Code	4224
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4224-10	10 in 1 BOX		
1	NDC:0986-4224-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141277	10/18/2012	

COMFORTIS

spinosad tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4225
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)	SPINOSAD	810 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics			
Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	18 mm

Flavor	MEAT (MEAT)	Imprint Code	4225	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4225-10	10 in 1 BOX		
1	NDC:0986-4225-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA141277		10/18/2012	

COMFORTIS

spinosad tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0986-4227
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SPINOSAD (UNII: XPA88EAP6V) (SPINOSAD - UNII:XPA88EAP6V)		SPINOSAD	1620 mg
Inactive Ingredients			
Ingredient Name			Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
WATER (UNII: 059QF0KO0R)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
Product Characteristics			
Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	22mm
Flavor	MEAT (MEAT)	Imprint Code	4227
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0986-4227-10	10 in 1 BOX		
1	NDC:0986-4227-06	1 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA		NADA141277	10/18/2012	

Labeler - Elanco Animal Health Co (807447169)

Establishment			
Name	Address	ID/FEI	Business Operations
Abbvie Inc		078458370	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Dow Agrosciences, LLC		837038785	API MANUFACTURE